LAW OFFICES

HYMAN, PHELPS & MCNAMARA, P.C.

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MARC H. SHAPIRO
FRANCES K. WU

ROBERT T. ANGAROLA
(1945-1996)

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D. C. 20005-5929
(202) 737-5600
FACSIMILE
(202) 737-9329
www.hpm.com

JENNIFER B. DAVIS
OF COUNSEL

DAVID B. CLISSOLD
CASSANDRA A. SOLTIS
JOSEPHINE M. TORRENTE
MICHELLE L. BUTLER
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LARRY K. HOUCK
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KURT R. KARST
MOLLY C. ANDRESEN
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JULIE C. KLISH*

*NOT ADMITTED IN DC

DIRECT DIAL (202) 737-4280

December 17, 2004

BY FACSIMILE/CONFIRMATION COPY BY MAIL

Mr. Timothy A. Ulatowski
Director, Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
2094 Gaither Road, Room 244
Rockville, Maryland 20850 HFZ-300

Dear Mr. Ulatowski:

Enclosed are communications sent by two reprocessors, notifying customers that FDA has determined that devices reprocessed by them are not considered to be substantially equivalent to cleared devices. SterilMed, Inc. and Vanguard Medical Concepts, Inc. sent the notices. Both are challenges to FDA, defying the agency in two important ways.

First, the communications declare that their products are safe and effective, notwithstanding that FDA has not found their products to be substantially equivalent to any predicate devices. Products which are not substantially equivalent to predicate devices are adulterated if they are introduced into interstate commerce without premarket approval by FDA. See 21 U.S.C. § 351(f)(1)(B); 21 U.S.C. § 360c(f). Is FDA willing to permit recalled products, adulterated products, to be called "safe and effective?" Is it not presumptuous for these companies to tell the hospitals that they need not be concerned because FDA will soon agree to allow the affected products to return to the market?

2004N-0154 C1

2603 MAIN STREET
SUITE 760
IRVINE, CALIFORNIA 92614
(949) 553-7400
FAX: (949) 553-7433

4819 EMPEROR BOULEVARD
SUITE 400
DURHAM, NORTH CAROLINA 27703
(919) 313-4750
FAX: (919) 313-4751

Second, the communications make no effort to comply with FDA's recall regulations. We understand that FDA has said the withdrawal of these NSE devices possibly may not be viewed to be a recall. Irrespective of that, there is doubt that the devices are adulterated. FDA at minimum should require that there be respect for 21 C.F.R. § 7.49 (c)(2), which specifically directs that "[t]he recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message." Both communications show no regard for this direction by FDA. In fact, the communications are promotional.

The SterilMed notice tells the hospitals "For over 90% of the devices reprocessed by SterilMed, there was no change in status." It goes on to say "it is important to note that these devices were previously cleared by the FDA and were found to be safe and effective as the original devices. Therefore, patient safety is not an issue." And the reason for the recall is obfuscated: "Since the affected devices no longer have 510(k) clearance, we are voluntarily removing them from the market in order to eliminate any confusion that this situation may create." However, the purpose of the recall is not to eliminate confusion.

Vanguard tells the hospitals that it "remains confident each of these devices is safe and efficacious for patient use based on our proven track record and the science behind the initial FDA 510(k) clearance." The company adds: "rest assured the Vanguard products on your shelves are safe and deliver the highest quality patient care." These are strong words of support for adulterated devices.

SterilMed and Vanguard do not agree with FDA's decision that their products are not substantially equivalent. This is evident in their communications, which are contemptuous of the law and regulations that FDA is bound to enforce. The appropriate agency response is to require prompt corrective messages from these companies, or for FDA itself to issue corrections.

Thank you for your attention to this matter.

Sincerely,

James R. Phelps

JRP/JMT/cld
Enclosures

STERILMED, INC.
Medical Device Reprocessing
Small Equipment & Instrument Repair

November 2004

CVL.

To: Materials Management, Operating Room, EP Lab and GI Lab Personnel

Subject: Voluntary market withdrawal notification

As you may know, as part of its implementation of the Medical Device User Fee and Modernization Act (MDUFMA), the FDA recently announced decisions regarding the 510(k) clearance of devices reprocessed by SterilMed. For over 90% of the devices reprocessed by SterilMed, there was no change in status. For the remaining devices, the FDA issued non-substantially equivalent (NSE) letters or SterilMed removed the devices from further consideration. SterilMed will need to provide additional technical information to the FDA in order to obtain 510(k) clearance for the NSE devices. Until we have that clearance, we are putting the affected devices on a regulatory hold, i.e. we will suspend reprocessing until further notice. However, it is important to note that these devices were previously cleared by the FDA and were found to be as safe and effective as the original devices. Therefore, patient safety is not an issue.

An account-specific list of affected devices is provided in the attached list.

On Tuesday, November 2, 2004, we stopped shipping both the affected devices. Any purchase orders you may have had in process have been adjusted accordingly. NOTE: this voluntary market withdrawal does not affect *any* open but unused devices reprocessed by SterilMed.

How You Are Affected

Since the affected devices no longer have 510(k) clearance, we are voluntarily removing them from the market in order to eliminate any confusion that this situation may create. Our sales representatives and On-Site Technicians (OSTs) will contact you in the next few days to arrange to have these devices returned to SterilMed. In the meantime, we will continue to collect the NSE devices so that we can protect your savings for the future.

Next Steps

To facilitate the withdrawal of affected devices from your inventory, please take the following steps:

1. Remove all affected devices from your shelves (see attached list). Hold them so that they can be returned to SterilMed. (NOTE: the complete list of affected model numbers can also be found on the customer log-in portion of our website at www.sterilmed.com. Log into "My SterilMed" and you will find the .PDF file entitled, "SterilMed NSE and removed devices 11.2004" in the "Customer Documents" area.)

2. Complete the attached Business Reply form and FAX it to SterilMed Customer Service at (763) 488-3350.

3. If your facility has any affected product in its inventory, your SterilMed sales representative will be in touch shortly to coordinate with you to identify, collect and ship back the affected devices from your account. You may also contact your Customer Service Specialist at (888) 541-0078 to obtain more information. You will receive credit for all returned devices.

We appreciate your business and the opportunity to serve you. Should you have any questions, or receive information from the original equipment manufacturer (OEM) that concerns you, please feel free to contact Doug Fletcher at (763) 488-3446 or Cathy Futrell at (763) 488-3442.

Sincerely,

Jeff Neichin

Jeff Neichin
Vice President, Sales and Marketing
SterilMed, Inc.

STERILMED, INC.
Trusted Name Representing
Small Equipment & Endoscopic Repair

This is an itemized list of affected devices SterilMed has shipped to you over the past 12 months.
You may use this as a guide to locate affected devices in your inventory for return to SterilMed.

Affected Device List						
CustomerID	AccountName	Device Type	Manufacturer	ManufacturersCatalogNo	SterilMedPartNumber	Total
194	Loma Linda Medical Center - Main	Diagnostic EP Cath	BIOSENSE WEBSTER	F6-QA-252-RT	BIOF6-QA-252-RT	17
				D6-DR-252-RT	BIOD6-DR-252-RT	57
				F5A-DP-P10-RT	BIOF5A-DP-P10-RT	22
				1086-259-RT	BIO1086-259-RT	13
			CORDIS WEBSTER	D6-06DR-002-RT	CORD6-06DR-002-RT	53
			EP TECHNOLOGIES	7003D	EPT7003D	4
		Endoscopic Trocars	ETHICON	355LD	ETH355LD	36
				355LM	ETH355LM	6
				355NS	ETH355NS	3
				355ST	ETH355ST	1
				35HLT	ETH35HLT	1
				35LST	ETH35LST	10
				35NLT	ETH35NLT	108
				35NST	ETH35NST	1
				511HT	ETH511HT	6
				511NT	ETH511NT	20
				5116D	ETH5116D	12
				5116M	ETH5116M	8
				511ST	ETH511ST	7
				512B	ETH512B	26
				512HT	ETH512HT	10
				512NT	ETH512NT	15
				512ON	ETH512ON	1
				5126D	ETH5126D	10
				5128L	ETH5128L	1
				5128M	ETH5128M	5
				512XD	ETH512XD	1
				5765D	ETH5765D	1
		ERCP Cannulas	MICROVASIVE	3088	MIC3088	1
				3097	MIC3097	1
194 Total						459

EQUIPMENT HAZARD NOTIFICATION PROGRAM (ALERTS)

Department: O.R., ECH O.R., E.R., Central Svc, Outpt. Surgery Ctr, UHC Purchasing, GI Lab, CH GI Lab, Cardiovascular Lab

FDA/ECRI#: Mfr 04-40

Date Sent: 12/2/2004

Alert#: 04-40

Hazard Classification: Serious

In compliance with Medical Center Policy T-23, we are alerting you to a possible equipment/product hazard as noted below. Thank you for your prompt attention to this matter.

1. Please check this recall alert and remove from service any equipment/product that is listed.
2. Take such actions as are appropriate, and document them below.
3. Complete and return this notice to the Office of Loss Control & Safety WITHIN 10 WORKING DAYS.
4. *PLEASE NOTE*: if you know of any department or area not listed above which should receive this notice please jot it down on this form.

_____ No action required. (You don't have any of the devices/products identified in the alert.)

_____ Action required/taken:

☐ Item(s) have been returned to manufacturer/sales representative.

☐ Item(s) need to be picked up for return to manufacturer. Original P.O. # _____

☐ Other action taken or required. Describe: _____

NAME _____ DEPT. _____ DATE: _____

SEE EQUIPMENT/PRODUCT DESCRIPTION ON NEXT PAGE

For MS&D use only: Above item(s) returned by _____ on _____

VANGUARD

November 11, 2004

Dear Vanguard Customer,

As you are aware during the past year Vanguard and the rest of the reprocessing industry have been working to meet the requirements of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). Prior to the passage of this legislation, the FDA had cleared our products for marketing through its 510(k) clearance process.

MDUFMA added a second round of scrutiny that involved submitting supplemental validation submissions (SVS) to the FDA for certain devices that had already received 510(k) clearance. Vanguard has been extremely diligent in this matter and has met every deadline required by the FDA.

Now that the latest MDUFMA review is completed, we're pleased to tell you that 98.9% of Vanguard's product offerings are legally marketable. However, Vanguard and the other major reprocessors in the industry did not receive clearance for all devices that required submission of an SVS.

Along with the rest of the industry Vanguard is working with the FDA on the remaining few devices still not cleared. We look forward to a prompt resolution of the issue, and we fully expect to return those devices to the market in the near future.

Vanguard remains confident each of these devices is safe and efficacious for patient use based on our proven track record and the science behind the initial FDA 510(k) clearance. In the meantime, we are voluntarily withdrawing from the market those devices that have not yet received clearance, while we provide FDA with answers to additional technical questions. You know from your experience as a Vanguard customer that, as the industry leader, we do the right thing.

You should have or shortly will have the details of this voluntary market withdrawal. We appreciate your cooperation, apologize for any inconvenience and assure you that we are working diligently to resolve the issue as quickly as possible.

With more than 7,000 legally marketable reprocessed products in our catalog, rest assured the Vanguard products on your shelves are safe and deliver the highest quality patient care

Thank you for your continued support and confidence in Vanguard and the reprocessing industry.

Sincerely,

Charles A. Mazak
Chief Executive Officer

MEDICAL DEVICE VOLUNTARY MARKET WITHDRAWAL NOTIFICATION

PRODUCT	Vanguard manufactured trocars and ultrasonic scalpels (see attached list of affected product codes on page 4).
REASON	Vanguard is conducting a voluntary market withdrawal of Vanguard manufactured trocars and ultrasonic scalpels. Vanguard is voluntarily withdrawing these products as a result of receiving Non-Substantially Equivalent (NSE) letters on the Supplemental Validation Submissions (SVS) that it submitted pursuant to the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). However, please be aware that, prior to the passage of MDUFMA, Vanguard manufactured trocars and ultrasonic scalpels were determined by FDA to be as safe and effective as original devices, pursuant to the agency's traditional 510(k) clearance process. Vanguard will not ship these products until such time as we can provide answers to additional FDA technical questions and obtain market clearance.
ACTION	1. Immediately examine your inventory of Vanguard trocars and ultrasonic scalpels. 2. Remove and quarantine all affected products. 3. Complete the attached Action Acknowledgement Form (page 3 & 4 attached). If your facility has any affected product in inventory, please specify the quantity of each affected product code on the attached product list (Part II of the Action Acknowledgement Form). This form must be completed and returned to Vanguard, because Vanguard needs to document your receipt of this notification along with the type and number of units that you will be returning to Vanguard. ***Please FAX the completed Action Acknowledgement Form to Lee Rose, Vanguard Medical Concepts, Inc., at 863-904-2334.*** 4. Ship all affected product back to Vanguard using the following shipping information: Vanguard Medical Concepts, Inc. Attn: Lee Rose 5300 Region Court Lakeland, FL 33815-3113 5. Representatives from Vanguard Medical Concepts, Inc. can assist you, if needed, in returning all affected products to Vanguard and completing the Action Acknowledgement Form.
OTHER INFORMATION	Vanguard will process your return and issue facility credit for the returned devices as soon as we have received both the completed Action Acknowledgement Form and the affected devices. Please share this information with all appropriate staff at your facility. If you have additional questions about this action, please contact Lee Rose at (800) 887-9073.

[redacted]

...OL NUMBER: 200111111429
...TOMER NUMBER: FL230STMH
...STOMER NAME: TALLAHASSEE MEMORIAL HOSPITAL
ADDRESS: 1300 MICCOUSUKEE ROAD
CITY, STATE, ZIP TALLAHASSEE, FL 32308

PART II: LIST OF AFFECTED VANGUARD DEVICES

Original Mfg.	Catalog No	Description	Quantity
Trocars			
ETHICON	35HS	5mm Optical Trocar with Non-Bladed Obturator, Handled Smooth Sleeve, 75mm	
ETHICON	35NLT	5mm Optical Trocar w/Non-Bladed Obturator, Non-Handled Stability Sleeve, 100mm	
ETHICON	35NST	5mm Optical Trocar w/Non-Bladed Obturator, Non-Handled Stability Sleeve, 75mm	
ETHICON	35OL	5mm Optical Trocar w/Non-bladed Obturator, Non-Handled Smooth Sleeve 100mm	
ETHICON	35OS	5mm Optical Trocar w/Non-Bladed Obturator, Non-Handled Smooth Sleeve, 75mm	
ETHICON	511NT	10/11mm Optical Trocar w/Non-Bladed Obturator, Non-Handled Stability Sleeve, 100mm	
ETHICON	511O	10/11mm Optical Trocar w/Non-Bladed Obturator, Non-Handled Smooth Sleeve, 100mm	
ETHICON	512B	10/12mm Blunt Tip Trocar 100mm, with Plug	
ETHICON	512NT	10/12mm Optical Trocar w/Non-Bladed Obturator, Non-Handled Stability Sleeve, 100mm	
ETHICON	512ON	10/12mm Optical Trocar w/Non-Bladed Obturator, Non-Handled Smooth Sleeve, 100mm	
ETHICON	355L	5mm Pyramidal Blade Trocar Smooth Sleeve, 100mm	
ETHICON	355LD	5mm Dilating Tip Trocar Stability Sleeve, 100mm	
ETHICON	355LM	5mm Dilating Tip Trocar Smooth Sleeve, 100mm	
ETHICON	355S	5mm Pyramidal Blade Trocar Smooth Sleeve, 75mm	
ETHICON	355SD	5mm Dilating Tip Trocar Stability Sleeve, 75mm	
ETHICON	355SM	5mm Dilating Tip Trocar Smooth Sleeve, 75mm	
ETHICON	35ST	5mm Pyramidal Blade Trocar Integrated Stability Threads, 75mm	
ETHICON	35STM	5mm Dilating Tip Trocar Integrated Stability Threads, 75mm	
ETHICON	5116	10/11mm Pyramidal Blade Trocar Smooth Sleeve, 100mm	
ETHICON	5116D	10/11mm Dilating Tip Trocar Stability Sleeve, 100mm	
ETHICON	5116M	10/11mm Dilating Tip Trocar Smooth Sleeve, 100mm	
ETHICON	5126	10/12mm Pyramidal Blade Trocar Smooth Sleeve, 100mm	
ETHICON	5126D	10/12mm Dilating Tip Trocar Stability Sleeve, 100mm	
ETHICON	5126M	10/12mm Dilating Tip Trocar Smooth Sleeve, 100mm	
ETHICON	512XD	10/12mm Dilating Tip Trocar Smooth Sleeve, 150mm	
ETHICON	578SD	7/8mm Dilating Tip Trocar Stability Sleeve, 100mm	
ETHICON	T566	5mm Adjustable Stability Thread	
ETHICON	T611	10/11mm Adjustable Stability Thread	
ETHICON	T612	10/12mm Adjustable Stability Thread	
Ultrasonic Scalpels			
ETHICON	C514C	5mm Coagulating Shears Scissor Grip, 14cm long Curved Active Blade	
ETHICON	C523C	5mm Coagulating Shears Scissor Grip, 23cm long Curved Active Blade	
ETHICON	LCSB5	5mm Coagulating Shears Pistol Grip, 36cm long Blunt Active Blade	
ETHICON	LCSC5	5mm Coagulating Shears Pistol Grip, 36cm long Curved Active Blade	
ETHICON	LCSK5	5mm Coagulating Shears Pistol Grip, 36cm long Knife-Down Active Blade	

Please list the Acknowledgment Number found at the top of this form on the outside of all shipping boxes used to comply with this request. Please include a copy of the Action Acknowledgement Form (Part I) and a list of returned products (Part II) within the box.

[redacted]

...OL NUMBER: 2004111111429
...TOMER NUMBER: FL2308TMH
...USTOMER NAME: TALLAHASSEE MEMORIAL HOSPITAL
ADDRESS: 1300 MICCOUSKEE ROAD
CITY, STATE, ZIP TALLAHASSEE, FL 32308

PART II: LIST OF AFFECTED VANGUARD DEVICES

Original Mfg.	Catalog No	Description	Quantity
Trocars			
ETHICON	35HS	5mm Optical Trocar with Non-Bladed Obturator, Handled Smooth Sleeve, 75mm	
ETHICON	35NLT	5mm Optical Trocar w/Non-Bladed Obturator, Non-Handled Stability Sleeve, 100mm	
ETHICON	35NST	5mm Optical Trocar w/Non-Bladed Obturator, Non-Handled Stability Sleeve, 75mm	
ETHICON	35OL	5mm Optical Trocar w/Non-bladed Obturator, Non-Handled Smooth Sleeve 100mm	
ETHICON	35OS	5mm Optical Trocar w/Non-Bladed Obturator, Non-Handled Smooth Sleeve, 75mm	
ETHICON	511NT	10/11mm Optical Trocar w/Non-Bladed Obturator, Non-Handled Stability Sleeve, 100mm	
ETHICON	511O	10/11mm Optical Trocar w/Non-Bladed Obturator, Non-Handled Smooth Sleeve, 100mm	
ETHICON	512B	10/12mm Blunt Tip Trocar 100mm, with Plug	
ETHICON	512NT	10/12mm Optical Trocar w/Non-Bladed Obturator, Non-Handled Stability Sleeve, 100mm	
ETHICON	512ON	10/12mm Optical Trocar w/Non-Bladed Obturator, Non-Handled Smooth Sleeve, 100mm	
ETHICON	355L	5mm Pyramidal Blade Trocar Smooth Sleeve, 100mm	
ETHICON	355LD	5mm Dilating Tip Trocar Stability Sleeve, 100mm	
ETHICON	355LM	5mm Dilating Tip Trocar Smooth Sleeve, 100mm	
ETHICON	355S	5mm Pyramidal Blade Trocar Smooth Sleeve, 75mm	
ETHICON	355SD	5mm Dilating Tip Trocar Stability Sleeve, 75mm	
ETHICON	355SM	5mm Dilating Tip Trocar Smooth Sleeve, 75mm	
ETHICON	355T	5mm Pyramidal Blade Trocar Integrated Stability Threads, 75mm	
ETHICON	355TM	5mm Dilating Tip Trocar Integrated Stability Threads, 75mm	
ETHICON	511S	10/11mm Pyramidal Blade Trocar Smooth Sleeve, 100mm	
ETHICON	511SD	10/11mm Dilating Tip Trocar Stability Sleeve, 100mm	
ETHICON	511SM	10/11mm Dilating Tip Trocar Smooth Sleeve, 100mm	
ETHICON	512S	10/12mm Pyramidal Blade Trocar Smooth Sleeve, 100mm	
ETHICON	512SD	10/12mm Dilating Tip Trocar Stability Sleeve, 100mm	
ETHICON	512SM	10/12mm Dilating Tip Trocar Smooth Sleeve, 100mm	
ETHICON	512XD	10/12mm Dilating Tip Trocar Smooth Sleeve, 150mm	
ETHICON	578SD	7/8mm Dilating Tip Trocar Stability Sleeve, 100mm	
ETHICON	T355	5mm Adjustable Stability Thread	
ETHICON	T511	10/11mm Adjustable Stability Thread	
ETHICON	T512	10/12mm Adjustable Stability Thread	
Ultrasonic Scalpels			
ETHICON	CS14C	5mm Coagulating Shears Scissor Grip, 14cm long Curved Active Blade	
ETHICON	CS23C	5mm Coagulating Shears Scissor Grip, 23cm long Curved Active Blade	
ETHICON	LCSB5	5mm Coagulating Shears Pistol Grip, 36cm long Blunt Active Blade	
ETHICON	LCSC5	5mm Coagulating Shears Pistol Grip, 36cm long Curved Active Blade	
ETHICON	LCSK5	5mm Coagulating Shears Pistol Grip, 36cm long Knife-Down Active Blade	

Please list the Acknowledgment Number found at the top of this form on the outside of all shipping boxes used to comply with this request. Please include a copy of the Action Acknowledgement Form (Part I) and a list of returned products (Part II) within the box.

[redacted]